WHAT IS CLAIMED IS:

1. Use of an approved drug product containing an anti-androgen for the manufacture of a medicament for treating non-metastatic castration-resistant prostate cancer wherein the approved drug product containing the anti-androgen is in a form suitable for administration to a male human with a non-metastatic castration-resistant prostate cancer in an amount that is described in a drug product label for said approved drug product.

2. The use of claim 1, wherein the non-metastatic castration-resistant prostate cancer is a high risk non-metastatic castration-resistant prostate cancer.

3. The use of claim 2, wherein the male human has said non-metastatic castration-resistant prostate cancer and has a prostate-specific antigen doubling time (PSADT) that is less than or equal to 10 months.

4. The use of any one of the preceding claims, wherein the male human having said non-metastatic castration-resistant prostate cancer has received at least one prior therapy for the treatment of cancer.

5. The use of claim 4, wherein the prior therapy for the treatment of cancer is bicalutamine or flutamide.

6. The use of any one of claims 1 to 3, wherein the male human having said non-metastatic castration-resistant prostate cancer is treatment naïve.

7. The use of any one of the preceding claims, wherein the male human having said non-metastatic castration-resistant prostate cancer is an adult.

8. The use of any one of the preceding claims, wherein the medicament is intended to provide an increase in the metastasis-free survival of the male human.

9. The use of any one of the preceding claims, the medicament is intended to provide improved anti-tumor activity as measured by time to metastasis (TTM), progression-free survival (PFS) rate, time to symptomatic progression, overall survival (OS) rate, or time to initiation of cytotoxic chemotherapy.

10. The use of any one of the preceding claims, wherein administration of the medicament will result in no more than a grade 3 adverse event.

11. The use of any one of the preceding claims, wherein the anti-androgen is a second-generation anti-androgen.

12. The use of claim 11, wherein the anti-androgen is apalutamide darolutamide, or enzalutamide.

13. The use of claim 12, wherein the anti-androgen is enzalutamide.

14. The use of claim 12, wherein the anti-androgen is apalutamide.

15. The use of claim 13, wherein the medicament containing enzalutamide is to be administered daily to the male human.

16. The use of claim 14, wherein the medicament containing apalutamide is to be administered daily to the male human.

17. The use of claim 14, wherein the medicament containing apalutamide is to be administered orally on a continuous daily dosage schedule.

18. The use of claim 14, wherein the medicament containing apalutamide is to be administered orally at a dose of about 240 mg per day.

19. The use of claim 14, wherein the medicament containing apalutamide is to be administered orally at a dose of about 60 mg four times per day.

20. The use of claim 14, wherein the medicament is present in a solid dosage form.

21. The use of claim 20, wherein the medicament is formulated as a tablet.

22. The use of claim 14, wherein the amount of apalutamide that is to be administered is reduced when it is to be coadministered with one or more of:

(a) a CYP2C8 inhibitor, preferably gemfibrozil or clopidogrel; or

(b) a CYP3A4 inhibitor, preferably ketoconazole or ritonavir.

23. The use of claim 14, wherein the medicament containing apalutamide is not for use in combination with:

(a) medications that are primarily metabolized by CYP3A4, preferably darunavir, felodipine, midazolam or simvastatin;

(b) medications that are primarily metabolized by CYP2C19, preferably diazepam or omeprazole;

(c) medications that are primarily metabolized by CYP2C9, preferably warfarin or phenytoin; or

(d) medications that are substrates of UGT, preferably levothyroxine or valproic acid.

24. The use of claim 14, wherein the medicament containing apalutamide is not for use in combination with:
(a) medications that are P-gp substrates, preferably fexofenadine, colchicine, dabigatran etexilate or digoxin; or
(b) BCRP/OATP1B1 substrates, preferably lapatinib, methotrexate, rosuvastatin, or repaglinide.

25. A method of selling an approved drug product comprising apalutamide, said method comprising selling such drug product, wherein a drug product label for a reference listed drug for such drug product includes instructions for treating non-metastatic castration resistant prostate cancer.

26. The method of claim 25, wherein the drug product is an ANDA drug product, a supplemental New Drug Application drug product or a 505(b)(2) drug product.

27. A method of offering for sale an approved drug product comprising apalutamide, said method comprising offering for sale such drug product, wherein a drug product label for a reference listed drug for such drug product includes instructions for treating non-metastatic castration resistant prostate cancer.

28. The method of claim 27, wherein the drug product is an ANDA drug product, a supplemental New Drug Application drug product or a 505(b)(2) drug product.

29. A method of selling an approved drug product comprising apalutamide, said method comprising selling such drug product, wherein the drug product label for a reference listed drug for such drug product comprises metastasis free survival data.

30. The method of claim 29, wherein the metastasis free survival data for apalutamide in combination with androgen deprivation therapy arm has a median of about 40.5 months.

31. A method of offering for sale an approved drug product comprising apalutamide, said method comprising offering for sale such drug product, wherein the drug product label for a reference listed drug for such drug product comprises metastasis free survival data.

32. The method of claim 31, wherein the metastasis free survival data for apalutamide in combination with androgen deprivation therapy arm has a median of about 40.5 months

33. Use of an approved drug product comprising apalutamide for the manufacture of a medicament for improving metastasis free survival in a male human with non-metastatic castration-resistant prostate cancer wherein the approved drug product comprising apalutamide is in a form suitable for provision to said male human in combination with androgen deprivation therapy.

34. The use of claim 33, wherein the median metastasis free survival is about 40.5 months.

35. The use of claim 33 or claim 34, wherein the approved drug product is an ANDA drug product or a supplemental New Drug Application drug product.

36. The use of any one of claims 33 to 35, wherein the drug product label for a reference listed drug for such drug product includes instructions for treating non-metastatic castration resistant prostate cancer.

37. An approved drug product with at least one approved indication, wherein said approved drug product comprises apalutamide.

38. An approved drug product of claim 37, wherein the approved drug product is a NDA drug product, an ANDA drug product, a supplemental New Drug Application drug product, or a 505(b)(2) drug product.

39. An approved drug product of claim 37, wherein a reference listed drug product for the approved drug product includes a drug product label.

40. An approved drug product of claim 39, wherein the drug product label comprises metastasis free survival data.

41. An approved drug product of claim 40, wherein the metastasis free survival data for apalutamide in combination with androgen deprivation therapy arm has a median of about 40.5 months.